Use of the DAYTRANA® (methylphenidate transdermal system) Patch

The Daytrana patch contains a prescription central nervous system (brain) stimulant medicine used to treat ADHD in children and adolescents 6 to 17 years old. Use of the Daytrana patch may help increase attention and decrease impulsive or hyperactive behavior. The Daytrana patch should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Important Safety Information

IMPORTANT: Daytrana is a controlled substance (CII) because it can be abused or lead to dependence. Keep Daytrana in a safe place to protect it from theft. Selling or giving away Daytrana may harm others and is against the law. Tell the prescribing doctor if your child has ever been abused or dependent on alcohol, prescription medicines or street drugs.

The Daytrana patch should not be used if your child has been diagnosed as very anxious, tense, or agitated; has an eye problem called glaucoma; has tics (repeated movements or sounds that cannot be controlled); has a diagnosis or family history of Tourette’s syndrome; is taking a monoamine oxidase inhibitor (MAOI) medicine or has discontinued an MAOI medicine in the last 2 weeks; or is allergic to methylphenidate, acrylic adhesive, or any other ingredients in the Daytrana patch. Do not use Daytrana if you have had a heart attack or stroke or have heart problems (such as severe high blood pressure or a heart block). Daytrana is not for use in treating heart problems.

Serious heart problems have been reported with the Daytrana patch or other stimulant medicines including:

• sudden death in people with heart problems or heart defects
• stroke and heart attack in adults
• increased blood pressure and heart rate

Tell the doctor if you or your child has any heart problems, heart defects, or increased blood pressure and heart rate. Remove the Daytrana patch and call the doctor right away if your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while using Daytrana. Before you start using Daytrana, tell your doctor if you have circulation problems in your fingers or toes. Call the doctor right away if you, your child, or a family member has a history of vitiligo.

Tell the doctor about any mental problems your child or family members have experienced including suicide or depression, bipolar illness, mania, or psychosis. Call the doctor right away if your child has any new or worsening mental symptoms or problems while using the Daytrana patch. Tell your doctor if you, your child, or a family member has a history of violent behavior.

Be sure to tell the doctor if your child is pregnant or breast feeding.

Serious side effects such as seizures (this usually happens in children with a history of seizures), painful and prolonged erections (priapism), slowing of speech or writing, weight gain, loss of skin color (chemical leukoderma) and eyeight changes or blurred vision have been reported with the Daytrana patch. Because of the potential for lasting damage, seek medical help immediately if you or your child develops priapism. Your child should have their height, weight, and blood work checked while using the Daytrana patch and the doctor may stop treatment if a problem is found during these check-ups. Allergic skin rash may occur. Stop using the Daytrana patch and see the doctor right away if swelling, bumps, or blisters happen at or around the site where the patch is applied. If the patch is worn longer than 9 hours a day, or more than 1 patch is worn at a time, too much medicine has been applied. Avoid exposing the Daytrana patch to direct external heat sources such as hair dryers, heat pad, electric blankets, heated water beds, or other heat sources while wearing the patch. Heating the patch could cause too much medicine to pass into your child’s body and cause serious side effects.

The most common side effects seen while using the Daytrana patch include skin problems (redness, small bumps, itching) where the patch is applied, trouble appetite, nausea, vomiting, stomach pain, weight loss, trouble sleeping, mood swings, and dizziness.

Please read Medication Guide and Full Prescribing Information including the Boxed Warning regarding abuse and dependence.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/medwatch or call 1-800-FDA-1088.

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